Exactech® Gibralt™ Spinal System
Traditional 510(k)

K110197

510(k) Summary

JUL 15 2011

Company: Exactech®, Inc
2320 NW 66th Court
Gainesville, FL 32653

Date: January 21, 2011

Contact Person: Vladislava Zaitseva

Regulatory Affairs Specialist
Phone: (352) 377-1140
Fax: (352) 378-2617

Proprietary Name: Exactech® Gibralt™ Spinal System

Common Name: Spinal Fixation System

Classification Name:

- 21 CFR 888.3070 - Pedicle screw spinal system, Class II, Product Code: MNI - Orthosis, Spinal Pedicle Fixation
- 21 CFR 888.3050 - Spinal interlaminal fixation orthosis, Class II, Product Code: KWP - appliance, fixation, spinal interlaminal

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- S4 Spinal System (K050979)
- Vertex Reconstruction System (K003780)
- CerviFix - Axon System (K991089/K023675)

Device Description

This submission proposes a new spinal fixation system. The proposed Gibralt Spinal System is a top-loading spinal fixation system that comprises various sizes of polyaxial screws, rods, hooks, and various connectors to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the cervical, and/or upper thoracic spine. The Gibralt Spinal System components are manufactured from titanium alloy per ASTM F136. The system components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

The Gibralt Spinal System includes a complete instrumentation system to assist the surgeon in the implantation of each component according to a traditional open surgical procedure.

Indications for Use

When intended to promote fusion of the cervical spine, and the thoracic spine, (C3-T3), the Gibralt Spinal System is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),

K110197

spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C3-T3) spine.

The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Polyaxial screws are not intended to be placed in the cervical spine.

This system can be used independently or in conjunction with Exactech 5.5mm or 6.0mm rod-based Thoraco-Lumbar Pedicle Screw Systems.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use/Indications for Use.**
  The Gibralt Spinal System has the equivalent indications for use and intended uses as the sited predicates.

- **Materials**
  The Gibralt Spinal System and predicates are composed of titanium alloy, a biocompatible material conforming to a recognized industry standard for permanent implants.

- **Design Features**
  The Gibralt Spinal System and predicates have similar design features.

- **Dimensions**
  The Gibralt Spinal System and predicates are dimensionally comparable.

- **Packaging and Sterilization**
  The Gibralt Spinal System and predicates are provided non-sterile for single use only, and will be steam sterilized by the hospital prior to use in the operating room using the same method.

- **Device Shelf Life**
  Neither the Gibralt Spinal System nor cited predicates have shelf life expiration dating.

- **Performance specifications**
  The Gibralt Spinal System and cited predicates all withstand clinically relevant biomechanical loads.

K110197

Substantial Equivalence Conclusion

The following mechanical testing and engineering analysis were conducted to demonstrate substantial equivalence of the proposed Gibralt Spinal System to the predicates:

- Rod-to-rod connector Flexural Grip and Torsion Grip testing in accordance with ASTM F1798.
- Static Compression Bending, Static Torsion, and Dynamic Compression bending testing in accordance with ASTM F1717.
- A biomechanical assessment comparing Gibralt Spinal System mechanical performance to cited predicate devices.

The results of mechanical testing and analysis demonstrate that the proposed devices are substantially equivalent to cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Ms. Vladislava Zaitseva
Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

JUL 15 2011

Re: K110197
Trade/Device Name: Exactech® Gibralt™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: June 15, 2011
Received: June 16, 2011

Dear Ms. Zaitseva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Gibralt™ Spinal System
Traditional 510(k)

Indications for Use Statement

510(k) Number: K 110197

Device Name: Exactech® Gibralt™ Spinal System

INDICATIONS FOR USE:
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Prescription Use __X__ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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